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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/467,368

Applicant(s)

Hansen et al.

Examiner

Manjunath N. Rao

Group Art Unit

1652



☒ Responsive to communication(s) filed on Dec 20, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 19-29 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 19-29 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Claims 19-29 are now pending in this application.

Election/Restriction

2. This application contains claims directed to the following patentably distinct species of the claimed invention: *Humicola*, *Thermoascus*, *Chaetomium*, *Mucor*, *Talaromyces*, *Malbranchea*, *Myceliophthera*, *Thielavia*, *Byssoschlamus*, *Paecilomyces* and *Thermomyces*.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. During a telephone conversation with Elias Lambiris on 10-16-2000 a provisional election was made with traverse to prosecute the invention of species *Thermomyces*.

Affirmation of this election must be made by applicant in replying to this Office action. Claim withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 22-24 recite xylanases as derived from strains without referring to any species of the numerous genera recited in claim 21 which is unclear to the Examiner.

7. Claims 22-24 are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It appears that claims 22-24 recite names of families (Pyrenomycetes and Plectomycetes) and the name of the order Eriotiales as name of strains which is again unclear to the Examiner as to the exact nature of the applicant's claim. Furthermore even if the applicants were actually claiming strains belonging to the respective "families" and "order", claims 22-24 would be considered as indefinite as succeeding claim 24 would be directed to a broader limitation than a narrower limitation (family) of preceding claims 22-23.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 19-25 and claims 25-29 depending from claim 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a xylanase from *Thermomyces lanuginosus* (also known as *Humicola lanuginosus*) strain DSM 4109, does not

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reasonably provide enablement for any xylanase enzyme having a pH optimum in the range of 4.5-7.5 and a residual activity after incubation for 60 minutes at pH 6.0 as recited in claim 1, from any source including natural or recombinant plants, animals, microorganisms such as any bacteria, fungi, thermophilic fungi or yeasts etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 19-25 are so broad as to encompass any xylanase enzyme from any natural or recombinant source. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of xylanase enzymes broadly encompassed by the claims. Since the amino acid sequence of a protein and extent of purity of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and to obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to a single xylanase enzyme of *Thermomyces lanuginosus*.

While enzyme isolation techniques and recombinant techniques are known, it is not routine in the art to screen multiple sources, as encompassed by the instant claims, and the reasonable expectation of success in obtaining the desired enzyme are limited due to the

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complexity of the huge number of sources that need to be analyzed and the result of such isolation from an extremely large number of sources is unpredictable.

The specification does not support the broad scope of the claims which encompass all xylanase enzymes of any source because the specification does **not** establish: (A) a rational and predictable scheme for isolation and characterization of any xylanase from any given source with an expectation of obtaining the desired biological activity and function; (B) the specification provides insufficient guidance as to which of the infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any xylanase enzyme isolated from any source. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

10. Claims 19-25 and claims 25-29 depending from claim 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

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such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 19-25 are directed to an isolated and purified enzyme endowed with a xylanase activity only. The specification discloses that the enzyme was derived from *Thermomyces lanuginosus*. Claims 19-25 are rejected under this section of 35 USC 112 because the claim is directed to all xylanase enzymes from all natural or recombinant sources. No description has been provided of the xylanase enzyme from all the other sources as encompassed by the claim. Applicants have not adequately described the types of sources in which the enzyme is present nor have they provided any information regarding isolation, purification and characterization of the enzyme from the innumerable number of sources available. No structural information, beyond the characterization of the enzyme from a single source (*T.lanuginosus*) has been provided by Applicants which would indicate that they had possession of all the claimed enzymes, i.e. the enzyme corresponding to all sources. Since the claimed enzyme from all sources beyond that of its recitation in the claim exists and no enzyme from any other source has been determined, a person having ordinary skill in the art would not recognize that Applicants had possession of the claimed invention at the time of filing. Thus, while the argument may be made that claims 19-25 are enabled for an isolated xylanase from *T.lanuginosus*, Applicants have not shown that they were in possession of all the xylanase enzymes from all the sources at the time of filing.

Claims 19-25 are directed to a xylanase enzyme which has a pH optimum range of 4.5-7.5 and a residual activity as recited in claim 1. The specification discloses that the enzyme was

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derived from *T.laniginosus*. Claims 19-25 are rejected under this section of 35 USC 112 because the claims are directed to all types of xylanase enzymes that fall under the above characteristics only. No description has been provided of any other xylanase enzyme with the recited characteristics from any other sources. It is not clear to the Examiner as to how the applicants differentiate between their invention and any other xylanase enzyme that may be present in *T.lanuginosus* itself or any other source just based on the functional property and source, or function. Applicants have not adequately described the specific characteristics of their invention by way of for example, amino acid sequence information, nor have they provided any information regarding isolation, purification and characterization of the different types of xylanase enzyme that may occur in *Humicola lanuginosus*. No structural information, beyond the characterization of a single enzyme has been provided by Applicants.

In *Vas-Cath Inc. v. Mahurkar* (CA FC) 19 USPQ2d 1111 the court held that: Written description of invention required by first paragraph of 35 USC 112 is separate and distinct from that paragraph's requirement of enabling disclosure, since description must do more than merely provide an explanation of how to "make and use" invention; applicant must also convey, with reasonable clarity to those skilled in the art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed.

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Claim Rejections - 35 USC § 102/103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102/103 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 19-25 and claims 26-29 which depend on claim 19 are rejected under 35 U.S.C. 102(b) as anticipated by Lischnig et al. (Biotechnology letters, 1993, Vol. 15(4):411-414) or Gomes et al. (Appl. Microbiol. Biotechnol., 1993, Vol. 39:700-707) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lischnig et al. or Gomes et al. and Alam et al. (Enzyme Microb. Technol., 1994, Vol. 16, pages 298-302). This rejection is based on the public availability of printed document regarding xylanase enzyme.

Claims 19-29 of the instant application are drawn to a xylanase enzyme isolated from *Humicola lanuginosa* which has a pH optimum in the range of 4.5-7.5 with a residual activity as disclosed in claim 19 and its use as an animal feed additive. According to applicants own admission, the xylanase enzyme of *Humicola lanuginosa* was known in the prior art as preparations described by Lischnig et al. or Gomes et al. (See page 1, line 28-33) and its use in

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animal feed (Alam et al. page 2, lines 5-11 of the specification) . Therefore the xylanase enzyme of the instant application anticipates the xylanase enzyme of the reference. Even if applicants argue that the enzyme of the reference was not a monocomponent xylanase and was a crude mixture, it would be obvious for one skilled in the art to use the knowledge existing in the field of enzyme purification, at the time the application was filed, and purify the xylanase to homogeneity. Thus Lischnig et al. or Gomes et al. and Alam et al. anticipates claims 19-25 or make them *prima facie* obvious as written.

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014.

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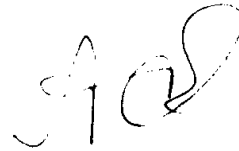
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Manjunath N. Rao

December 1, 2000



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